

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION**

**MDL NO. 1968**

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**THIS DOCUMENT RELATES TO ALL CASES**

**MYLAN DEFENDANTS' ANSWER TO PLAINTIFFS'  
MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS**

Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc., and UDL Laboratories, Inc. (collectively "Mylan Defendants"), by and through their counsel, respond to the allegations set forth in Plaintiffs' Master Consolidated Complaint for Individuals ("Master Complaint") as follows:

Plaintiffs' Master Complaint improperly mixes factual averments with argumentative rhetoric so as to make admissions or denials of such averments difficult or impossible. Accordingly, by way of a general response, all allegations are denied unless specifically admitted, and any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, or speculations which are contained in the averment or in the Master Complaint as a whole.

**I. ANSWER TO SECTION I (INTRODUCTION)**

1. Mylan Defendants admit that Plaintiffs bring their Master Complaint for various claims related to the marketing, designing, manufacturing, producing, supplying, inspecting, testing, selling and distributing of Digitek®. Mylan Defendants deny any allegations or averments set forth in Paragraph 1 of the Master Complaint.

## **II. ANSWER TO SECTION II (PARTIES)**

### **A. PLAINTIFFS**

2. Mylan Defendants admit that Paragraph 2 of the Master Complaint states that it is brought on behalf of all plaintiffs who were prescribed, purchased and ingested Digitek®, as well as their spouses and/or family members. Mylan Defendants deny any allegations or averments set forth in Paragraph 2 of the Master Complaint.

### **B. DEFENDANTS**

3. The allegations and averments set forth in Paragraph 3 of the Master Complaint are directed to defendants other than Mylan Defendants and, therefore, no response is required. To the extent a response is deemed necessary, Mylan Defendants state that they lack knowledge or information sufficient to form a belief as to the truth of the allegations and averments set forth in Paragraph 3 and, therefore, deny the same.

4. The allegations set forth in Paragraph 4 of the Master Complaint are directed to defendants other than Mylan Defendants and, therefore, no response is required. To the extent a response is deemed necessary, Mylan Defendants state that they lack knowledge or information sufficient to form a belief about the truth of the allegations and averments set forth in Paragraph 4 and, therefore, deny the same.

5. The allegations set forth in Paragraph 5 of the Master Complaint are directed to defendants other than Mylan Defendants and, therefore, no response is required. To the extent a response is deemed necessary, Mylan Defendants state that they lack knowledge or information sufficient to form a belief about the truth of the allegations and averments set forth in Paragraph 5 and, therefore, deny the same.

6. Mylan Defendants admit that Mylan Inc. is a Pennsylvania corporation and further answering, deny each and every remaining allegation and averment in Paragraph 6 of the Master Complaint.

7. Mylan Defendants admit that Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business located in Morgantown, West Virginia and that Mylan Pharmaceuticals Inc. began distributing Digitek® in 2005. Mylan Defendants deny each and every remaining allegation and averment in Paragraph 7 of the Master Complaint.

8. Mylan Defendants admit that Mylan Bertek Pharmaceuticals Inc. is a Texas corporation and that Mylan Bertek Pharmaceuticals Inc. distributed Digitek® from 1999 until 2005. Mylan Defendants deny each and every remaining allegation and averment in Paragraph 8 of the Master Complaint.

9. Mylan Defendants admit that UDL Laboratories, Inc. is an Illinois corporation and that UDL Labs began distributing Digitek® in 1999. Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 9 of the Master Complaint.

### **III. ANSWER TO SECTION III (JURISDICTION AND VENUE)**

10. Mylan Defendants admit that diversity jurisdiction appears to exist and state that they are not contesting subject matter jurisdiction at this time.

11. Mylan Defendants admit that the Master Complaint purports to be drafted and filed in accordance with Pre-Trial Order #11. Mylan Defendants further admit that, per Pre-Trial Order #19, they have agreed—solely for the purpose of consolidated discovery and related pretrial proceedings—to waive their defense of improper venue in cases filed directly into MDL 1968 or into the United States District Court for the Southern District of West Virginia (“direct filed” cases). Mylan Defendants admit that for direct-filed cases, the defense of improper venue for the purpose of trial is not waived and will be asserted on a case-by-case basis, as Mylan

Defendants deem appropriate. To the extent that the remaining jurisdictional allegations set forth in Paragraph 11 of the Master Complaint pertain to direct-filed cases, Mylan Defendants deny the same.

**IV. ANSWER TO SECTION IV (FACTUAL ALLEGATIONS)**

**A. THE DRUG - DIGITEK® (DIGOXIN)**

12. Mylan Defendants admit that Digitek® is a cardiac glycoside. Mylan Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations and averments set forth in Paragraph 12 and, therefore, deny the same.

13. Mylan Defendants admit that Mylan Bertek Pharmaceuticals Inc. distributed Digitek® from 1999 to 2005 and that Mylan Pharmaceuticals Inc. began distributing Digitek® under a Bertek label in 2005. Further, Mylan Defendants admit that UDL Laboratories, Inc. began distributing Digitek® in 1999. To the extent that the remaining allegations and averments set forth in Paragraph 13 of the Master Complaint are directed to them, Mylan Defendants deny the same.

14. Mylan Defendants admit that Digitek® is indicated for the treatment of heart failure and atrial fibrillation and that the Food and Drug Administration (“FDA”) approved the sale of 0.125 mg and 0.250 mg dosages of Digitek®. Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 14 of the master Complaint.

15. Mylan Defendants admit that FDA approved the sale of Digitek® tablets containing 0.125 mg and 0.250 mg of digoxin. Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 15 of the Master Complaint.

16. Mylan Defendants admit that FDA approved the sale of Digitek® tablets containing 0.125 mg and 0.250 mg of digoxin. Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 16 of the Master Complaint.

17. Mylan Defendants admit that digoxin overdose and digitalis toxicity can cause health problems and even death but deny that any of the injuries, losses and damages Plaintiffs' allege were directly or proximately caused by Digitek®. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 17 of the Master Complaint.

**B. THE FDA WARNING LETTERS**

18. Mylan Defendants admit that on August 1, 2008, Actavis Totowa LLC issued a voluntary recall of all drug products, including Digitek®, manufactured at its Little Falls, New Jersey facility. Mylan Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations and averments set forth in Paragraph 18 of the Master Complaint and, therefore, deny the same.

19. Mylan Defendants state that the August 15, 2006 warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 19 of the Master Complaint.

20. Mylan Defendants state that the content of the FDA's website speaks for itself and deny any allegations and averments set forth in Paragraph 20 of the Master Complaint.

21. Mylan Defendants state that the August 15, 2006 warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 21 of the Master Complaint.

22. Mylan Defendants state that the August 15, 2006 warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 22 of the Master Complaint.

23. Mylan Defendants state that the August 15, 2006 warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 23 of the Master Complaint.

24. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 24 of the Master Complaint.

25. Mylan Defendants deny each and every allegation contained in Paragraph 25 of the Master Complaint.

26. Mylan Defendants state that the regulations described in Paragraph 26 of the Master Complaint speak for themselves and deny any allegations and averments set forth in Paragraph 26.

27. Mylan Defendants state that the content of the FDA's website speaks for itself and deny any allegations and averments set forth in Paragraph 27 of the Master Complaint.

28. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 28 of the Master Complaint.

29. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 29 of the Master Complaint.

30. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 30 of the Master Complaint.

31. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 31 of the Master Complaint.

32. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 32 of the Master Complaint.

33. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 33 of the Master

Complaint.

34. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 34, including subsections (a)-(f), of the Master Complaint.

35. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 35 of the Master Complaint.

36. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 36 of the Master Complaint.

37. Mylan Defendants state that the February 1, 2007 revised warning letter speaks for itself and deny any allegations and averments set forth in Paragraph 37 of the Master Complaint.

### **C. THE RECALL**

38. Mylan Defendants admit that, on April 25, 2008, a Class I Recall of lots of Digitek® was announced. Mylan Defendants state that the April 25, 2008 FDA Alert speaks for itself and deny each and every remaining allegation and averment set forth in Paragraph 38 of the Master Complaint.

39. Mylan Defendants state the content of the FDA's website speaks for itself and deny each and every remaining allegation and averment set forth in Paragraph 39 of the Master Complaint.

40. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 40 of the Master Complaint.

41. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 41, including subsections (a)-(d), of the Master Complaint.

42. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 42 of the Master Complaint.

43. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 43, including subsections (a)-(l), of the Master Complaint.

44. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 44 of the Master Complaint.

45. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations and averments set forth in Paragraph 45 and, therefore, deny the same.

46. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations and averments set forth in Paragraph 46 regarding other Defendants. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 46 of the Master Complaint.

47. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 47 of the Master Complaint.

48. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 48 of the Master Complaint.

49. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 49 of the Master Complaint.

50. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 50 of the Master Complaint.



51. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 51 of the Master Complaint.

52. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 52 of the Master Complaint.

53. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 53 of the Master Complaint.

**V. ANSWER TO SECTION V (CLAIMS FOR RELIEF)**

**COUNT ONE: FAILURE TO WARN AND INSTRUCT**

54. In response to Paragraph 54 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 53 of the Master Complaint, as fully set forth herein.

55. Mylan Defendants admit that Mylan Bertek Pharmaceuticals Inc. distributed Digitek® from 1999 to 2005 and that Mylan Pharmaceuticals Inc. began distributing Digitek® under a Bertek label in 2005. Further, Mylan Defendants admit that UDL Laboratories, Inc. began distributing Digitek® in 1999. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 55 of the Master Complaint.

56. Mylan Defendants admit that Digitek® tablets were expected to reach patients without a substantial change in their condition from the time they were distributed. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 56 of the Master Complaint.

57. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 57 of the Master Complaint.

58. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 58 of the Master Complaint.

59. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations regarding the manner in which Plaintiffs used Digitek® and, therefore, deny the same. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 59 of the Master Complaint.

60. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 60 of the Master Complaint.

61. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 61 of the Master Complaint.

62. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 62 of the Master Complaint.

63. Mylan Defendants state that they were subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 63 of the Master Complaint to the extent that they suggest any different or greater duties. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 63.

64. Mylan Defendants deny each and every allegation contained in Paragraph 64 of the Master Complaint.

65. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 65 of the Master Complaint.

#### **COUNT TWO: MANUFACTURING DEFECT**

66. In response to Paragraph 66 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 65 of the Master Complaint, as fully set forth herein.

67. Mylan Defendants admit that Mylan Bertek Pharmaceuticals Inc. distributed Digitek® from 1999 to 2005 and that Mylan Pharmaceuticals Inc. began distributing Digitek®

under a Bertek label in 2005. Further, Mylan Defendants admit that UDL Laboratories, Inc. began distributing Digitek® in 1999. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 67 of the Master Complaint.

68. Mylan Defendants admit that Digitek® tablets were expected to reach patients without a substantial change in their condition from the time they were distributed. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 68 of the Master Complaint.

69. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 69 of the Master Complaint.

70. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 70 of the Master Complaint.

71. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 71 of the Master Complaint.

72. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations regarding the manner in which Plaintiffs used Digitek® and, therefore, deny the same. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 72 of the Master Complaint.

73. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 73 of the Master Complaint.

### **COUNT THREE: DESIGN DEFECT**

74. In response to Paragraph 74 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 73 of the Master Complaint, as fully set forth herein.

75. Mylan Defendants admit that Mylan Bertek Pharmaceuticals Inc. distributed Digitek® from 1999 to 2005 and that Mylan Pharmaceuticals Inc. began distributing Digitek® under a Bertek label in 2005. Further, Mylan Defendants admit that UDL Laboratories, Inc. began distributing Digitek® in 1999. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 75 of the Master Complaint.

76. Mylan Defendants admit that Digitek® tablets were expected to reach patients without a substantial change in their condition from the time they were distributed. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 76 of the Master Complaint.

77. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 77 of the Master Complaint.

78. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 78, including subsections (a)-(e), of the Master Complaint.

79. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations regarding the manner in which Plaintiffs used Digitek® and, therefore, deny the same. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 79 of the Master Complaint.

80. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 80 of the Master Complaint.

81. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 81 of the Master Complaint.

**COUNT FOUR: NEGLIGENCE**

82. In response to Paragraph 82 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 81 of the Master Complaint, as fully set forth herein.

83. Mylan Defendants state that they were subject only to those duties imposed by applicable law and deny the allegations set forth in Paragraph 83 of the Master Complaint to the extent that they suggest any different or greater duties. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 83.

84. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 84, including subsections (a)-(i), of the Master Complaint.

85. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 85 of the Master Complaint.

86. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 86 of the Master Complaint.

87. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 87 of the Master Complaint.

88. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 88 of the Master Complaint.

**COUNT FIVE: NEGLIGENCE *PER SE***

89. In response to Paragraph 89 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 88 of the Master Complaint, as fully set forth herein.

90. Mylan Defendants state that they were subject only to those duties and obligations imposed by applicable law and deny the allegations set forth in Paragraph 90 of the Master

Complaint to the extent that they suggest any different or greater duties or obligations. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 90.

91. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 91 of the Master Complaint.

92. Paragraph 92 of the Master Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Mylan Defendants deny any allegations and averments and averment set forth in Paragraph 92.

93. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 93 of the Master Complaint.

94. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 94 of the Master Complaint.

95. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 95 of the Master Complaint.

96. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 96 of the Master Complaint.

97. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 97 of the Master Complaint.

#### **COUNT SIX: BREACH OF IMPLIED WARRANTY**

98. In response to Paragraph 98 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 97 of the Master Complaint, as fully set forth herein.

99. Paragraph 99 of the Master Complaint contains legal conclusions to which no response is required. To the extent that a response is deemed required, Mylan Defendants deny any allegations and averments and averment set forth in Paragraph 99.

100. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 100 of the Master Complaint.

101. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 101 of the Master Complaint.

102. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 102 of the Master Complaint.

103. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 103 of the Master Complaint.

#### **COUNT SEVEN: BREACH OF EXPRESS WARRANTY**

104. In response to Paragraph 104 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 103 of the Master Complaint, as fully set forth herein.

105. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 105 of the Master Complaint.

106. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 106 of the Master Complaint.

107. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 107 of the Master Complaint.

108. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 108 of the Master Complaint.

109. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 109 of the Master Complaint.

**COUNT EIGHT: NEGLIGENT MISREPRESENTATION**

110. In response to Paragraph 110 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 109 of the Master Complaint, as fully set forth herein.

111. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 110 of the Master Complaint.

112. Mylan Defendants admit that they were subject only to those duties imposed by applicable law and deny that any such duties were breached. Mylan Defendants deny each and every remaining allegation in Paragraph 112 of the Master Complaint.

113. Mylan Defendants state that they were subject only to those duties and obligations imposed by applicable law and deny the allegations set forth in Paragraph 113 of the Master Complaint to the extent that they suggest any different or greater duties or obligations. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 113.

114. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 114 of the Master Complaint.

115. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 115 of the Master Complaint.

116. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 116 of the Master Complaint.

117. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 117 of the Master Complaint.



**COUNT NINE: MISREPRESENTATION**

118. In response to Paragraph 118 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 117 of the Master Complaint, as fully set forth herein.

119. Mylan Defendants state that they were subject only to those duties and obligations imposed by applicable law and deny the allegations set forth in Paragraph 119 of the Master Complaint to the extent that they suggest any different or greater duties or obligations. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 119.

120. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 120 of the Master Complaint.

121. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 121, including subsections (a)-(d), of the Master Complaint.

122. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 122 of the Master Complaint.

123. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 123 of the Master Complaint.

124. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 124 of the Master Complaint.

125. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 125 of the Master Complaint.

126. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 126 of the Master Complaint.

**COUNT TEN: FRAUD**

127. In response to Paragraph 127 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 126 of the Master Complaint, as fully set forth herein.

128. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 128 of the Master Complaint.

129. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 129, including subsections (a)-(d), of the Master Complaint.

130. Mylan Defendants state that they were subject only to those duties and obligations imposed by applicable law and deny the allegations set forth in Paragraph 130 of the Master Complaint to the extent that they suggest any different or greater duties or obligations. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 130.

131. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 131 of the Master Complaint.

132. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 132 of the Master Complaint.

133. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 133 of the Master Complaint.

134. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 134 of the Master Complaint.

135. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 135 of the Master Complaint.

136. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 136 of the Master Complaint.

**COUNT ELEVEN: CONSTRUCTIVE FRAUD**

137. In response to Paragraph 137 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 136 of the Master Complaint, as fully set forth herein.

138. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 138 of the Master Complaint.

139. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 139 of the Master Complaint.

140. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 140 of the Master Complaint.

141. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 141 of the Master Complaint.

142. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 142 of the Master Complaint.

143. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 143 of the Master Complaint.

**COUNT TWELVE: VIOLATION OF WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT (WEST VIRGINIA CODE § 46A-6-101, ET SEQ)**

144. In response to Paragraph 144 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 143 of the Master Complaint, as fully set forth herein.

145. Paragraph 145 contain a legal conclusion to which no response is required. To the extent that a response is deemed required, Mylan Defendants deny any allegations and averments set forth in Paragraph 145.

146. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 146 of the Master Complaint.

147. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 147 of the Master Complaint.

148. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 148 of the Master Complaint. To the extent that Paragraph 148 contains legal conclusions, Mylan Defendants state that no answer is required.

149. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 149 of the Master Complaint.

150. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 150 of the Master Complaint.

**COUNT THIRTEEN: VIOLATION OF APPLICABLE CONSUMER PROTECTION  
AND/OR UNFAIR TRADE PRACTICES STATUTES**

151. In response to Paragraph 151 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 150 of the Master Complaint, as fully set forth herein.

152. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the averments concerning the number of states that have enacted consumer protection statutes and , therefore, deny the same. Further answering, Mylan Defendants deny each and every remaining allegation and averment set forth in Paragraph 152 of the Master Complaint.

153. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 153, including subsections (a)-(yy), of the Master Complaint.

154. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 154 of the Master Complaint.

#### **COUNT FOURTEEN: WRONGFUL DEATH**

155. In response to Paragraph 155 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 154 of the Master Complaint, as fully set forth herein.

156. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 156 of the Master Complaint.

157. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 157 of the Master Complaint.

158. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations and averments set forth in Paragraph 158 of the Master Complaint and, therefore, deny the same.

159. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 159 of the Master Complaint.

#### **COUNT FIFTEEN: SURVIVAL ACTION**

160. In response to Paragraph 160 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 159 of the Master Complaint, as fully set forth herein.

161. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 161 of the Master Complaint.

162. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations and averments set forth in Paragraph 162 of the Master Complaint and, therefore, deny the same.

163. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 163 of the Master Complaint.

#### **COUNT SIXTEEN: MEDICAL MONITORING**

164. In response to Paragraph 164 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 163 of the Master Complaint, as fully set forth herein.

165. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 165 of the Master Complaint.

166. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 166 of the Master Complaint.

167. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 167 of the Master Complaint.

168. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 168 of the Master Complaint.

#### **COUNT SEVENTEEN: UNJUST ENRICHMENT**

169. In response to Paragraph 169 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 168 of the Master Complaint, as fully set forth herein.

170. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 170 of the Master Complaint.

171. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 171 of the Master Complaint.

172. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 172 of the Master Complaint.

173. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 173 of the Master Complaint.

**COUNT EIGHTEEN: MEDICARE SECONDARY PAYER ACT**

174. In response to Paragraph 174 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 173 of the Master Complaint, as fully set forth herein.

175. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 175 of the Master Complaint. To the extent that Paragraph 175 contains legal conclusions, Mylan Defendants state that no answer is required.

**COUNT NINETEEN: LOSS OF CONSORTIUM**

176. In response to Paragraph 176 of the Master Complaint, Mylan Defendants reassert and incorporate by reference their answers to Paragraphs 1 through 175 of the Master Complaint, as fully set forth herein.

177. Mylan Defendants state that they are without knowledge or information sufficient to form a belief about the truth of the allegations and averments set forth in Paragraph 177 of the Master Complaint and, therefore, deny the same.

178. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 178 of the Master Complaint.

179. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 179 of the Master Complaint.

180. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 180 of the Master Complaint.

181. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 181 of the Master Complaint.

182. Mylan Defendants deny each and every allegation and averment set forth in Paragraph 182 of the Master Complaint.

Mylan Defendants demand a jury trial on all issues so triable.

**FIRST AFFIRMATIVE DEFENSE**

The Master Complaint fails to state a claim or claims upon which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**

Some or all of Plaintiffs' claims are barred by the statute of limitations and/or statute of repose.

**THIRD AFFIRMATIVE DEFENSE**

Some or all of Plaintiffs' claims are barred by the doctrines of waiver, laches, and/or estoppel.

**FOURTH AFFIRMATIVE DEFENSE**

Some or all of Plaintiffs' claims are barred by the doctrines of informed consent and release.

**FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs are barred, in whole or in part, from asserting each alleged cause of action in the Master Complaint, or otherwise asserting any right to relief against Mylan Defendants, because any losses or damages suffered by Plaintiffs were not directly or proximately caused by any conduct, action, or omission on the part of Mylan Defendants.



**SIXTH AFFIRMATIVE DEFENSE**

If Plaintiffs suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were the direct and proximate result of responsible, superseding, intervening, and/or illegal causes, or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, or independent or far removed from Mylan Defendants' conduct or control.

**SEVENTH AFFIRMATIVE DEFENSE**

The injuries and damages claimed by Plaintiffs, if any, were caused in whole or in part by the negligence, fault, or other culpable conduct of persons other than Mylan Defendants, or otherwise by the acts or omissions of persons over whom Mylan Defendants have no control or right of control.

**EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because Mylan Defendants acted in good faith at all times and gave adequate warnings of all known or reasonably knowable risks associated with the use of Digitek®.

**NINTH AFFIRMATIVE DEFENSE**

Plaintiffs' alleged injuries may be the result of idiosyncratic reactions to the product, or pre-existing and/or unrelated medical or genetic conditions for which Mylan Defendants are not responsible.

**TENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims should be dismissed, reduced, offset, or barred in accordance with any and all applicable principles of comparative negligence.

**ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims should be dismissed, reduced, offset, or barred in accordance with any and all applicable principles of contributory negligence in failing to exercise due and proper care under the circumstances and conditions.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiffs failed to exercise reasonable care and diligence to mitigate injuries and damages, if any.

**THIRTEENTH AFFIRMATIVE DEFENSE**

The injuries and damages alleged by Plaintiffs are or may be due to Plaintiffs' assumption of the risk of use of Digitek®, if any, thereby barring Plaintiffs from recovery.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by Plaintiffs' abuse and/or misuse of Digitek®.

**FIFTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the "state of the art" and "state of scientific knowledge" defenses.

**SIXTEENTH AFFIRMATIVE DEFENSE**

The duty to warn, if any, extends only to Plaintiffs' physicians and not directly to Plaintiffs. Therefore, Plaintiffs' claims are barred in whole or in part by the Learned Intermediary Doctrine.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or in part because Digitek® was at all times properly prepared, labeled, packaged and distributed, and was not defective or unreasonably dangerous.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

The United States Food and Drug Administration (“FDA”) approved the labeling for Digitek®, and the marketing and/or distributing of Digitek® conformed with FDA requirements regarding generic drug products and all other applicable statutes at all times pertinent to the Master Complaint.

**NINETEENTH AFFIRMATIVE DEFENSE**

Because FDA approved Digitek®, Plaintiffs’ claims that Mylan Defendants are strictly liable are barred under Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

**TWENTIETH AFFIRMATIVE DEFENSE**

Digitek® was safe when used as directed, and Mylan Defendants reasonably assumed that the warnings would be read and heeded; therefore, the product is neither defective nor unreasonably dangerous pursuant to Restatement (Second) of Torts § 402A, Comment j.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs’ claims are preempted by state and federal law and any regulations or rules promulgated thereunder, including the Federal Food and Drug and Cosmetic Act and amendments thereto. The granting of the relief prayed for would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. IV, Clause 2) of the United States Constitution.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

The Master Complaint and each of its causes of action are barred by the doctrine of immunity for prescription drugs, by the Commerce Clause, Article I, Section 8, of the Constitution of the United States as an undue burden upon interstate commerce and/or by the

preemption doctrine in that Plaintiffs have asserted claims for relief which, if granted, would constitute an impermissible burden by this court on federal laws, regulations and policy relating to the development and marketing of prescription drugs in violation of the Supremacy Clause, Article IV, Clause 2 of the Constitution of the United States.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's LegalComm.*, 531 U.S. 341 (2001).

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Any imposition of punitive damages in this case against Mylan Defendants is barred to the extent that the manner in which such punitive damages are calculated violates the Constitution of the United States and/or the Constitution of the state whose law is deemed to apply.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

Any award of punitive damages in this case against Mylan Defendants is barred to the extent that the amount of such an award violates the Constitution of the United States and/or the Constitution of the state whose law is deemed to apply.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Mylan Defendants did not make to Plaintiffs nor did they breach any express or implied warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity

with Mylan Defendants and/or for failure of Plaintiffs, or Plaintiffs' representatives, to give timely notice to Mylan Defendants of any alleged breach of warranty. Mylan Defendants further specifically plead as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future, as enacted in the states whose laws are deemed to apply in these cases.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because the advertisements and labeling with respect to Digitek® were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

Mylan Defendants did not violate any unfair or deceptive trade practice acts or other statutes under state law and/or these acts and statutes are not applicable to these matters and/or to these Plaintiffs.

**THIRTIETH AFFIRMATIVE DEFENSE**

Plaintiffs' claims and/or alleged damages are barred and/or limited by the provisions of the tort reform acts and/or statutes enacted in the states whose laws are deemed to apply in these cases.

**THIRTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs have failed to plead intentional misrepresentation and concealment, negligent misrepresentation and concealment, fraud and deceit, misrepresentation by omission and constructive fraud, with specificity.

**THIRTY-SECOND AFFIRMATIVE DEFENSE**

Mylan Defendants are entitled to setoffs for all amounts paid, payable by or available from collateral sources.

**THIRTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs' claims should be diminished in whole or in part in the amounts paid to Plaintiffs by any party or non-party with whom Plaintiffs have settled or may settle.

**THIRTY-FOURTH AFFIRMATIVE DEFENSE**

To the extent Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Mylan Defendants' rights under the United States Constitution.

**THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims against Mylan Defendants are barred because Mylan Defendants did not design, manufacture, alter or modify Digitek®, exercised no control over the warnings accompanying Digitek®, made no representations regarding Digitek®, and were unaware of any defect in Digitek®.

**THIRTY-SIXTH AFFIRMATIVE DEFENSE**

Mylan Defendants are entitled to, and claim the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of the state in which the cause of action arose or any other law or statute that may be applicable.

**THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by Plaintiffs' failure to comply with conditions precedent to their rights to recover.

**THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

Plaintiffs' Master Complaint is defective in that Plaintiffs have failed to join necessary or indispensable parties.

**THIRTY-NINTH AFFIRMATIVE DEFENSE**

Mylan Defendants hereby raise, assert, and preserve their defense of insufficiency of process.

**FORTIETH AFFIRMATIVE DEFENSE**

Mylan Defendants hereby raise, assert, and preserve their defense of insufficiency of service of process.

**FORTY-FIRST AFFIRMATIVE DEFENSE**

Mylan Defendants hereby raise, assert, and preserve their defense of improper venue.

**FORTY-SECOND AFFIRMATIVE DEFENSE**

Mylan Defendants hereby raise, assert, and preserve their right to invoke the doctrine of *forum non conveniens*.

**FORTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiffs lack standing to pursue their claims and/or seek the requested relief.

**FORTY-FOURTH AFFIRMATIVE DEFENSE**

All or part of Plaintiffs' claims are subject to the primary jurisdiction of FDA.

**FORTY-FIFTH AFFIRMATIVE DEFENSE**

Some or all of Plaintiffs' claims are barred due to spoliation of evidence.

**FORTY-SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims under the West Virginia Consumer Protection Act are barred by Plaintiffs' failure to comply with the notice requirements under West Virginia Code § 46A-6-106(b).

**FORTY-SEVENTH AFFIRMATIVE DEFENSE**

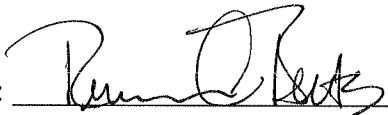
To the extent not incorporated above, Mylan Defendants raise all affirmative defenses available under the laws of the state in which the alleged causes of action arose.

**FORTY-EIGHTH AFFIRMATIVE DEFENSE**

Mylan Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional facts are obtained.

**WHEREFORE**, having fully answered, Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Bertek Pharmaceuticals Inc., and UDL Laboratories, Inc. specifically controvert the Prayer for Relief in the Master Complaint, including Paragraphs 1 through 10, and respectfully ask this Court to dismiss Plaintiffs' Master Consolidated Complaint for Individuals with prejudice, to assess costs against Plaintiffs, and to grant Mylan Defendants all other relief, in law or equity, to which they may be entitled.

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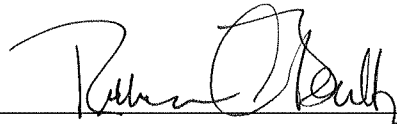
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**CERTIFICATE OF SERVICE**

I hereby certify that on April 20, 2009, I electronically filed the foregoing "Mylan Defendants' Answer to Plaintiffs' Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

A handwritten signature in black ink, appearing to read "Rebecca A. Betts", is written over a horizontal line.

REBECCA A. BETTS (WVSB # 329)

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